

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/929,819	EMANUELE	
	<b>Examiner</b> Richard Schnizer, Ph. D	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/31/05.
2. ☒ The allowed claim(s) is/are 1-5, 7-13 and 15-28.
3. ☒ The drawings filed on 14 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
|---|---|

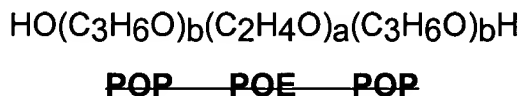
### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jamie Greene on 2/16/05.

The application has been amended as follows:

1. (Currently Amended) A composition comprising,  
one or more nucleic acid sequences or one or more triplex DNA compounds, and  
a nonionic block copolymer, wherein the block copolymer has the following formula:



wherein "b" represents a number such that the molecular weight of the hydrophobe  $(\text{C}_3\text{H}_6\text{O})_b$  is between approximately 750 and 20,000 Daltons, and "a" represents a number such that the percentage of hydrophile  $(\text{C}_2\text{H}_4\text{O})_a$  is between approximately 1% and 90% of the weight of the block copolymer and wherein the composition further comprises approximately 0.1% to approximately 5% by weight of a surfactant and approximately 0.5% to approximately 5% by volume of a low molecular weight alcohol.

2. (Previously Presented) The composition of Claim 1, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(\text{C}_3\text{H}_6\text{O})_b$  is between approximately 750 and 10,000 Daltons, and "a" represents a

number such that the percentage of hydrophile  $(C_2H_4O)_a$  is between approximately 1% and 90% of the weight of the block copolymer.

3. (Previously Presented) The composition of Claim 1, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(C_3H_6O)_b$  is between approximately 2,000 and 10,000 Daltons.

4. (Previously Presented) The composition of Claim 1, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(C_3H_6O)_b$  is approximately 2500 Daltons, and "a" represents a number such that the percentage of hydrophile  $(C_2H_4O)_a$  is approximately 10% of the weight of the block copolymer.

5. (Previously Presented) The composition of Claim 1, wherein the one or more nucleic acid sequences are selected from genes, oligonucleotides, antisense oligonucleotides, or ribozymes.

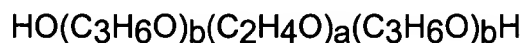
6. (Cancelled)

7. (Previously Presented) The composition of Claim 1, wherein the surfactant is polyoxyethylene (20) sorbitan monooleate and the alcohol is ethanol.

8. (Previously Presented) The composition of Claim 1, further comprising an expression vector capable of expressing the one or more nucleic acid sequences.

9. (Currently Amended) A method of delivering one or more nucleic acid sequences to an animal comprising,

administering to the animal a composition comprising one or more nucleic acid sequences or one or more triplex DNA compounds, and a nonionic block copolymer, wherein the block copolymer has the following formula:



wherein "b" represents a number such that the molecular weight of the hydrophobe  $(\text{C}_3\text{H}_6\text{O})_b$  is between approximately 750 and 20,000 Daltons, and "a" represents a number such that the percentage of hydrophile  $(\text{C}_2\text{H}_4\text{O})_a$  is between approximately 1% and 90% of the weight of the block copolymer and wherein the composition further comprises approximately 0.1% to approximately 5% by weight of a surfactant and approximately 0.5% to approximately 5% by volume of a low molecular weight alcohol.

10. (Previously Presented) The method of Claim 9, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(\text{C}_3\text{H}_6\text{O})_b$  is between approximately 750 and 10,000 Daltons, and "a" represents a number such that the percentage of hydrophile  $(\text{C}_2\text{H}_4\text{O})_a$  is between approximately 1% and 90% of the weight of the block copolymer.

11. (Previously Presented) The method of Claim 9, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(\text{C}_3\text{H}_6\text{O})_b$  is between approximately 2,000 and 10,000 Daltons, and "a" represents a number such that the percentage of hydrophile  $(\text{C}_2\text{H}_4\text{O})_a$  is between approximately 1% and 90% of the weight of the block copolymer.

12. (Previously Presented) The method of Claim 9, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(\text{C}_3\text{H}_6\text{O})_b$  is approximately 2500 Daltons, and "a" represents a number such that the percentage of hydrophile  $(\text{C}_2\text{H}_4\text{O})_a$  is approximately 10% of the weight of the block copolymer.

13. (Previously Presented) The method of Claim 9, wherein the one or more nucleic acid sequences are selected from genes, oligonucleotides, antisense oligonucleotides, or ribozymes.

14. (Cancelled)

15. (Previously Presented) The method of Claim 9, wherein the surfactant is polyoxyethylene (20) sorbitan monooleate and the alcohol is ethanol.

16. (Previously Presented) The method of Claim 9, wherein the composition further comprises an expression vector capable of expressing the one or more nucleic acid sequences.

17. (Currently Amended) The composition of Claim 1, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(C_3H_6O)_b$  is between approximately ~~3,250~~ 2,500 and ~~20,000~~ 8,500 Daltons.

18. (Currently Amended) The composition of Claim 1, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(C_3H_6O)_b$  is between approximately ~~5,000~~ 3,000 and ~~20,000~~ 7,000 Daltons.

19. (Currently Amended) The composition of Claim 1, wherein:

"b" represents a number such that the molecular weight of the hydrophobe  $(C_3H_6O)_b$  is between approximately ~~7,000~~ 5,000 and ~~20,000~~ 6,000 Daltons.

20. (Previously Presented) The composition of Claim 17, wherein the one or more nucleic acid sequences are selected from genes, oligonucleotides, antisense oligonucleotides, or ribozymes.

21. (Currently Amended) The composition of Claim 1, wherein:

"a" represents a number such that the percentage of hydrophile (C<sub>2</sub>H<sub>4</sub>O)<sub>a</sub> is ~~greater than about 1% and less than 10%~~ between approximately 2% and 30% of the weight of the block copolymer.

22. (Currently Amended) The composition of Claim 1, wherein:

"a" represents a number such that the percentage of hydrophile (C<sub>2</sub>H<sub>4</sub>O)<sub>a</sub> is ~~greater than 80% and less than about 90%~~ between approximately 7% and 23% of the weight of the block copolymer.

23. (Currently Amended) The method of Claim 9, wherein:

"b" represents a number such that the molecular weight of the hydrophobe (C<sub>3</sub>H<sub>6</sub>O)<sub>b</sub> is between approximately ~~3,250~~ 2,500 and ~~20,000~~ 8,500 Daltons.

24. (Currently Amended) The method of Claim 9, wherein:

"b" represents a number such that the molecular weight of the hydrophobe (C<sub>3</sub>H<sub>6</sub>O)<sub>b</sub> is between approximately ~~5,000~~ 3,000 and ~~20,000~~ 7,000 Daltons.

25. (Currently Amended) The method of Claim 9, wherein:

"b" represents a number such that the molecular weight of the hydrophobe (C<sub>3</sub>H<sub>6</sub>O)<sub>b</sub> is between approximately ~~7,000~~ 5,000 and ~~20,000~~ 6,000 Daltons.

26. (Previously Presented) The method of Claim 23, wherein the one or more nucleic acid sequences are selected from genes, oligonucleotides, antisense oligonucleotides, or ribozymes.

27. (Currently Amended) The method of Claim 9, wherein:

"a" represents a number such that the percentage of hydrophile (C<sub>2</sub>H<sub>4</sub>O)<sub>a</sub> is ~~greater than about 1% and less than 10%~~ between approximately 2% and 30% of the weight of the block copolymer.

28. (Currently Amended) The method of Claim 9, wherein:

"a" represents a number such that the percentage of hydrophile (C<sub>2</sub>H<sub>4</sub>O)<sub>a</sub> is ~~greater than 80% and less than about 90%~~ between approximately 7% to about 23% of the weight of the block copolymer.

### ***Reasons for Allowance***

The amendments to claims 1 and 9 preclude an objection to undefined acronyms POE and POP. The amendments to claims 17-28 overcome the new matter rejection of record.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.


If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Art Unit: 1635

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.



**DAVE TRONG NGUYEN**  
**PRIMARY EXAMINER**